IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY, and RECEPTOS LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SYNTHON BV,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Bristol-Myers Squibb Company ("BMS") and Receptos LLC ("Receptos") (together, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Synthon BV ("Synthon"). This action relates to Abbreviated New Drug Application ("ANDA") No. 219236 submitted by Synthon to the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 219236, Synthon seeks approval to market capsules containing 0.23 mg, 0.46 mg, and 0.92 mg of ozanimod (the "Synthon ANDA Product") prior to the expiration of U.S. Patent No 11,680,050 (the "'050 patent"). The Synthon ANDA Product is a generic version of Plaintiffs' Zeposia® drug product.

PARTIES

3. BMS is a corporation organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08543.

4. Receptos is a limited liability company organized and existing under the laws of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08543. Receptos is an indirect wholly-owned subsidiary of BMS.

5. Plaintiffs are engaged in the business of creating, developing, and bringing to market pharmaceutical products to help patients treat serious diseases, including multiple sclerosis ("MS") and ulcerative colitis ("UC"). Plaintiffs sell Zeposia® in this judicial District and throughout the United States.

6. Upon information and belief, Synthon is a corporation organized and existing under the laws of the Netherlands, having a business address at Microweg 22, 6545 CM, Nijmegen, the Netherlands. Upon information and belief, Synthon is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the United States market and/or manufacturing active pharmaceutical ingredients for generic copies of branded pharmaceutical products for the United States market.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court as to Synthon under 28 U.S.C. §§ 1391(c)(3) because Synthon is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction, including in this District.

9. This Court has personal jurisdiction over Synthon by virtue of, *inter alia*, Synthon's systemic and continuous contacts with this jurisdiction. Upon information and belief, Synthon regularly does and/or solicits business, and derives substantial revenue from selling pharmaceutical products throughout the United States, including Delaware. Upon information and

belief, either directly or through its subsidiaries, agents, and/or affiliates, Synthon has received numerous FDA approvals to market and sell pharmaceutical products throughout the United States, including Delaware. Upon information and belief, Synthon derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

10. This Court also has personal jurisdiction over Synthon because Synthon has been and is engaging in activities directed toward infringement of the '050 patent, including in this District. Synthon has submitted an ANDA for a generic version of Plaintiffs' Zeposia® product, seeking approval from the FDA to market and sell Synthon's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Synthon intends to market and sell Synthon's ANDA Product upon receiving FDA approval. Upon information and belief, if and when the FDA approves Synthon's ANDA, Synthon's ANDA Product would, among other things, be marketed, distributed, and sold in Delaware, prescribed by physicians practicing in Delaware, and/or dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing its ANDA, Synthon has made clear that it intends to use its distribution channels to direct sales of Synthon's ANDA Product in the United States, including Delaware.

11. In addition, this Court has personal jurisdiction over Synthon because Synthon has repeatedly availed itself of the rights, privileges, and protections of this Court as a litigant in this District. For example, Synthon has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District and successfully transferring litigation to this District. *See, e.g.*, Synthon Defendants' Answer, Additional Defenses, and Counterclaims, *Teva Pharmaceuticals USA, Inc. et al. v. Doctor Reddy's Laboratories, Ltd. et al.*, Case No. 16-1267 (D. Del. Feb. 16,

2017), D.I. 29; Synthon Defendants' Motion to Dismiss or Alternatively, to Transfer, *Teva Pharmaceuticals, USA, et al., v. Synthon Pharmaceuticals Inc., et al.*, Case No. 17-390 (D. Del. Feb. 20, 2017), D.I. 44 (granting motion to transfer and transferring case to the District of Delaware on Mar. 31, 2017, D.I. 69).

12. This Court also has personal jurisdiction over Synthon pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Synthon is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Synthon has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Synthon satisfies due process.

13. On June 21, 2024, counsel for Synthon confirmed that Synthon will not contest personal jurisdiction or venue in this Court for purposes of this litigation.

THE '050 PATENT

14. On June 20, 2023, the U.S. Patent and Trademark Office duly and legally issued the '050 patent, titled "Crystalline Forms of Ozanimod and Ozanimod Hydrochloride, and Processes for Preparation Thereof." A true and correct copy of the '050 patent is attached hereto as Exhibit A.

15. The claims of the '050 patent are valid, enforceable, and not expired.

16. Receptos is the assignee of the '050 patent. Plaintiffs have the right to enforce the '050 patent.

PLAINTIFFS' ZEPOSIA® PRODUCT

17. BMS is the current holder of New Drug Application ("NDA") No. 209899, by which the FDA granted approval for the marketing and sale of capsules containing 0.23 mg, 0.46

mg, and 0.92 mg of ozanimod. The ozanimod tablets are marketed in the United States under the trade name "Zeposia®."

18. Zeposia® is a sphingosine 1-phosphate receptor modulator indicated for the treatment of: (1) relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults; and (2) moderately to severely active UC in adults. A copy of the complete prescribing information for Zeposia® is attached as Exhibit B.

19. The FDA's Orange Book lists U.S. Patent Nos. 8,481,573 ("'573 patent"), 8,796,318 ("'318 patent"), 9,382,217 ("'217 patent"), 10,239,846 ("'846 patent"), and the '050 patent as covering Zeposia® and its use.

INFRINGEMENT BY SYNTHON

20. By letter dated May 20, 2024, Synthon notified Plaintiff BMS that Synthon had submitted ANDA No. 219236 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) (the "Notice Letter"). Plaintiff BMS received the Notice Letter no earlier than May 21, 2024.

21. The Notice Letter states that Synthon seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Synthon ANDA Product before the expiration of the '050 patent. The Notice Letter does not address any other patent listed in the Orange Book as covering Zeposia® and its use. Upon information and belief, Synthon intends to, directly or indirectly, engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product upon receiving FDA approval and after the expiration of the '573, '318, '217, and '846 patents.

22. By submitting ANDA No. 219236, Synthon has necessarily represented to the FDA that the Synthon ANDA Product has the same active ingredient as Zeposia®, has the same dosage form, route of administration, and strength as Zeposia®, and is bioequivalent to Zeposia®.

23. Upon information and belief, Synthon is seeking approval to market the Synthon ANDA Product for the same approved indications as Zeposia®.

24. In the Notice Letter, Synthon states that its ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the claims of the '050 Patent are invalid under 35 U.S.C. §§ 102 and 103. The Notice Letter does not contest that the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product will infringe all claims of the '050 patent, including at least claim 1, to the extent that the claims are valid. Synthon did not offer confidential access to its ANDA No. 219236 in the Notice Letter.

25. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letter.

CLAIM FOR RELIEF
(INFRINGEMENT OF THE '050 PATENT)

26. Plaintiffs incorporate each of the above paragraphs 1 to 25 as though fully set forth herein.

27. Upon information and belief, Synthon's submission of ANDA No. 219236 to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product for use in accordance with its proposed label prior to the expiration of the '050 patent infringed one or more claims of the '050 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Synthon has not contested the infringement of any claim of the '050 patent to the extent that the patent's claims are valid.

28. Upon information and belief, Synthon's commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product for use in accordance with its proposed label prior to the expiration of the '050 patent, and/or its inducement or contribution to such conduct, would further infringe one or more claims of the '050 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. §§ 271(a), (b), and/or (c). Those activities would infringe, induce the infringement of, and/or contribute to the infringement of at least claim 1 the '050 patent.

29. Upon information and belief, upon FDA approval of Synthon's ANDA No. 219236, Synthon will infringe, either literally or under the doctrine of equivalents, one or more claims of the '050 patent, by making, using, offering to sell, selling, and/or importing the Synthon ANDA Product for use in accordance with its proposed label, or by actively inducing and contributing to infringement of the '050 patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court. Unless enjoined, those activities would infringe, induce the infringement of, and/or contribute to the infringement of at least claim 1 of the '050 patent.

30. Upon information and belief, the Synthon ANDA Product or its use in accordance with its proposed label satisfies each and every element of at least claim 1of the '050 patent.

31. Claim 1 of the '050 patent, which is representative for purposes of Synthon's infringement of the patent's claims, recites:

> A crystalline Form CS1 of ozanimod hydrochloride, wherein the X-ray powder diffraction pattern shows characteristic peaks at 2theta values of 26.1°±0.20°, 24.4°±0.20° and 20.1°±0.20° using CuKα radiation.

32. Upon information and belief, the Synthon ANDA Product contains a crystalline Form CS1 of ozanimod hydrochloride, wherein the X-ray powder diffraction pattern shows characteristic peaks at 2theta values of 26.1°±0.20°, 24.4°±0.20° and 20.1°±0.20° using CuKα

radiation. For example, the Notice Letter states the "[t]he drug product is a capsule that contains the hydrochloride salt of ozanimod as the active ingredient," Notice Letter at 1, and nowhere in the Notice Letter does Synthon contend that it does not infringe any valid claim of the '050 patent.

33. Upon information and belief, Synthon does not dispute that the commercial manufacture, use, offer to sell, sale, and/or importation of the Synthon ANDA Product would infringe a valid claim of the '050 patent.

34. Upon information and belief, Synthon, upon FDA approval, would promote the use of the Synthon ANDA Product to infringe one or more claims of the '050 patent, including by encouraging the use of the Synthon ANDA Product in accordance with its proposed label.

35. Synthon had knowledge of the '050 patent prior to the submission of its ANDA. For example, the '050 patent is listed in the FDA's Orange Book under the entry for Zeposia®, and Synthon cites both the '050 patent and the Orange Book listing in the Notice Letter.

36. Upon information and belief, Synthon is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or medical practitioners will prescribe and/or administer the Synthon ANDA Product in accordance with its proposed label and therefore will directly infringe one or more claims of the '050 patent.

37. The Synthon ANDA Product constitutes a material part of the invention claimed in the '050 patent, is especially adapted for use in infringing the claims of the '050 patent, and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the '050 patent are not invalid, are not unenforceable, and are infringed by Synthon 's submission of ANDA No. 219236 under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, and that Synthon's making, using, offering to

sell, and/or selling in the United States, and/or importing into the United States, the Synthon ANDA Product will infringe, induce the infringement of, and/or contribute to the infringement of the claims of the '050 patent under 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 219236 shall be a date which is not earlier than the expiration date of the '050 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Synthon, its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Synthon ANDA Product until after the expiration date of the '050 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

4. An order awarding Plaintiffs their costs in this litigation;

5. A finding that this is an exceptional case and awarding Plaintiffs their reasonable attorneys' fees, including under 35 U.S.C. § 285; and

6. Such further and other relief as this Court deems just and proper.

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